Related Medlearn Matters Article #: MM3811
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Related CR #: 3811

Expansion of Coverage for Percutaneous Transluminal Angioplasty (PTA)

Key Words

MM3811, CR3811, MM3489, CR3489, Percutaneous, Transluminal, Angioplasty, Carotid, Artery, Coverage, Stent, FDA-approved, Embolic, Stenosis, CEA, Comorbidities

Provider Types Affected

Hospitals, physicians, and suppliers billing Medicare carriers or Fiscal Intermediaries (FIs) for Percutaneous Transluminal Angioplasty (PTA) services provided to Medicare beneficiaries

Key Points

- The effective date for instruction is March 17, 2005.
- MM 3811 and related CR 3811 revise Medicare coverage of PTA of the carotid artery.
- Effective March 17, 2005 the Centers for Medicare & Medicaid Services (CMS) expanded the coverage of PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent with embolic protection for the following:
    - Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq$ 70%. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and embolic protection devices;
    - Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70% in accordance to the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare National Coverage Determination (NCD) Manual, Section 310.1), or according to the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual, Section 20.7); and
    - Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq$ 80% (according to the Category B IDE clinical trials regulation (42 CFR 405.201)), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or according to the NCD on CAS post-approval studies (Medicare NCD Manual, Section 20.7).
    - The appropriate documentation confirming that a patient is at high risk for CEA and records of the patient's symptoms of carotid artery stenosis should be available in the patient medical records prior to performing any procedure.

- Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon.
- All facilities must at least meet CMS's standards modeled in part on professional society statements on competency in order to receive coverage for CAS for high risk patients.
- If the stenosis is measured by ultrasound prior to the procedure, the degree of stenosis must be confirmed by angiography at the start of the procedure.
- The CAS should not proceed if the stenosis is determined to be less than 70% by angiography.
- For evaluation purposes, all facilities must provide written documentation to CMS indicating it meets one of the following criteria:
    - Was a FDA-approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER;
    - Is a FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;
    - Is a FDA-approved site for one or more FDA post-approval studies; or
    - Has provided a written affidavit to CMS affirming that the facility meets the minimum facility standards and the affidavit must include the facility's name and complete address, Medicare provider number, point-of-contact name and telephone number, CAS procedure data collection mechanism, and a senior facility administrative official's signature.
    - A new affidavit is required every 2 years.
    - The affidavit should be sent to:

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Important Links

http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/MM3811.pdf
http://www.cms.hhs.gov/manuals/pm_trans/R33NCD.pdf
http://www.cms.hhs.gov/coverage/carotid-stent-facilities.asp
http://www.cms.hhs.gov/medlearn/matters/mmarticles/2004/MM3489.pdf
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